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10/681,821

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Anant V. Hegde

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EXAMINER

STOKLOSA, JOSEPH A

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/681,821

Applicant(s)

HEGDE ET AL.

Examiner

Joseph Stoklosa

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 and 122-170 is/are pending in the application.
- 4a) Of the above claim(s) 40-121 and 171-232 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 and 122-170 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 9/29/2006 is acknowledged.
2. Claims 40-121 and 171-232 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/29/2006.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

4. A person shall be entitled to a patent unless –

5. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 14-15, 36-38, 122, 128-130, 150-152, 156, and 161-164, are rejected under 35 U.S.C. 102(b) as being anticipated by Franchi (US 6,030,335).

7. Franchi discloses an implantable heart assist pump comprising: a body (Fig. 1, 10) and a coupled membrane (Fig. 1, 18) with a stiffness less than the body (Col. 4, line 16-22), with a variable volume in between the membrane and body where the membrane volume varies when the cavity volume is deformed (Col. 3, 36-46). Franchi discloses the body is made of a rigid metal and the

membrane is made of an elastomer (Col. 4, 16-22). Franchi discloses the membrane and body are coupled to each other about the perimeter at the upstream and downstream ends (Col. 3, line 62-65; Fig. 1). Franchi discloses the perimeter of the body and the perimeter of the membrane to have similar and different shapes at times (Fig. 3, Fig. 5, Fig. 6, Fig. 10).

8. With regard to claims 128-130, Franchi further discloses a pump in communication with the device that is pulsatile in nature and relating to a systole, and the entire system being implantable (Col. 3, line 47-59). Franchi discloses a sensor configured to generate cardiac data (Col. 7, line 6-17).

9. With regard to claims 150-152, 156, 161-164, Franchi discloses a plurality of conduits (Fig. 4, 24) supplying fluid, such as saline (Col. 6, line 50), to the cavity of the device and returning fluid to the pump, as well as a fluid volume compensator that is in fluid flow path between the pump and the cavity, wherein the compensator adjust volume ported into the cavity and allow replenishment of the fluid system (Col. 3, line 47- Col. 4, line 15; Fig. 1, Fig. 4).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that

Art Unit: 3762

the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 4, 7-13, 16-25, 170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franchi.

13. With regard to claims 4, 7-11, and 170, Franchi discloses the claimed invention except for a first silicone elastomer and a second silicone elastomer with material properties of 5-50 A and 500% elongation of the first silicon elastomer and 65-95 A and 400% percent elongation of the second elastomer and a reinforcement of polyester, nylon, stainless steel, platinum or other alloys of the second elastomer layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Franchi with first silicone elastomer and a second silicone elastomer with material properties of 5-50 A and 500% elongation of the first silicon elastomer and 65-95 A and 400% percent elongation of the second elastomer with a reinforcement element of polyester, nylon, stainless steel, platinum or other alloys, since it has been held to be within general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416.

Art Unit: 3762

14. With regards to Claim 13, Franchi discloses the claimed invention except for the first and second layers to be of silicone neoprene and copolymers comprising styrene and butadiene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Franchi with the first and second layers to be of silicone neoprene and copolymers comprising styrene and butadiene, since it was known in the art that the first and second layers to be of silicone neoprene and copolymers comprising styrene and butadiene is used to provide a biocompatible elastically deformable material for use in a vascular assist device.

15. With regards to claims 16-20, Franchi discloses the claimed invention except for the dimensions of the first and second layer reference each other. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Franchi with the dimensions of the first and second layer reference each other since it has been held that where the general conditions of a claim disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

16. With regards to claims 21-22, Franchi discloses blood vessel to be the Aorta (abstract).

17. With regards to claims 23-25, Franchi discloses the claimed invention except for the device to be adapted to engage inter-costal arteries or veins, the superior vena cava, or the inferior vena cava. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

system as taught by Franchi with engaging inter-costal arteries or veins, the superior vena cava, or the inferior vena cava since such a modification would provide for assistance and pumping in other parts of the cardiovascular system to improve patient cardiac health.

18. In addition since the system disclosed by Franchi is capable of being used around the aorta, it would also be inherently capable of fitting around other blood vessels, such as the superior vena cava, since they are of similar size, shape and relative dimensions, relative to the size of the patient.

19. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Franchi in view of Asrican (US 4,192,293).

20. With regard to claim 39, Franchi discloses the claimed invention except for an expandable bladder disposed between the first and second layer. Asrican teaches that it is known to use a bladder to be inflated to force flow of blood. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Franchi with an expandable bladder as taught by Asrican, since such a modification would provide the system with an expandable bladder for providing expansion to deform the compliant first layer while at the same time acting as a closed fluid pressure system so as not to lose the hydraulic fluid.

21. Claims 123-127, 131-132, 134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franchi in view of Freed et al. (US 5,169,379).

22. With regard to claims 123-127, 131-132, 134, Franchi discloses the claimed invention but fails to disclose what kind of signal is obtained in the

Art Unit: 3762

system or if the signal is indicative of systole, diastole, aortic pressure, arterial pressure, or venous pressure from what kind of sensor. Freed teaches that it is known to observe aortic pressure, which is inherently indicative of systolic pressure, and arterial pressure, as set forth in Col. 6, line 46, for providing pumping parameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Franchi with a signal indicative of systole, diastole, aortic pressure, arterial pressure, or venous pressure, since it was known in the art that systole, diastole, aortic pressure, arterial pressure, or venous pressure, as taught by Freed, since such a modification would provide the system with signal is indicative of systole, diastole, aortic pressure, arterial pressure, or venous pressure from what kind of sensor for providing indication of cardiac performance and would provide data for the controller to determine whether or not to activate the pump.

23. Claims 153-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franchi in view of Kung (US 4,888,011).

24. With regard to claims 153-154, Franchi discloses the claimed invention but fails to teach a second diameter of the lumen of one of the conduits. Kung teaches that it is known to vary flow resistance through varying lumen dimensions as set forth in Col. 4, line 53, for providing increased flow resistance to maintain a desired flow direction. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Franchi with a second diameter of the lumen of one of the conduits, as taught by Kung, since such a modification would provide a second diameter

Art Unit: 3762

of the lumen of one of the conduits is used to provide varied flow resistance in order to provide a desired flow direction.

25. With regard to claim 157-160, Franchi discloses the claimed invention except for the use of gas as the fluid along with the material properties of the gas or specific gases. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Franchi since it was known in the art that the use of a gas along with the material properties of the gas or specific gases and the material properties of gas are used to provide a safe alternative to an actual liquid. IT has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

26. Claims 165-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franchi in view of Okuzumi (US 6,587,734).

27. With regard to claims 165-168, Franchi discloses the claimed invention except for coating the device with a material to enhance lubricity and reduce fluid loss. Okuzumi teach that it is known to coat a vascular assist device with a polyurethane to enhance lubricity and prevent loss of fluid as set forth in Col. 9, line 1-13, for providing increased lubricity so as not to rupture or shear vasculature. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Franchi with coating the device with a material to reduce fluid loss and provide lubricity, as taught by Okuzumi, since it was known in the art that coating the device with a

Art Unit: 3762

material to reduce fluid loss and provide lubricity is used for allowing easier application of the device and prevent future invasive procedures to address lost fluid and/or ruptured or sheared vasculature.

28. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franchi in view of Walsh et al (US 6,902,522).

29. Franchi discloses the claimed invention except for coating the device with a tissue growth polymer such as poly-lysine. Walsh teaches that it is known to use poly-lysine in coating a vascular assist device as set forth in Col. 19, line 1-21 to provide receptor cell recruitment and increase patient acceptance of the implant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Franchi with coating the device with a tissue growth polymer such as poly-lysine, since such a modification would provide the system with a device that is coated with tissue growth polymer such as poly-lysine for providing receptor cell recruitment and increase patient acceptance of the implant.

30. Claims 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Franchi in view of Jarvik (US 4,938,766).

31. Franchi discloses the claimed invention except for at least two tabs at a first end and a second end. Jarvik teaches that it is known to use tabs as set forth in Fig. 14, 29 for providing flattening of the vessel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Jarvik, since such a modification would provide for flattening the vessel for improved compliance.

Allowable Subject Matter

32. Claims 27-35, 135-149, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Stoklosa whose telephone number is 571-272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

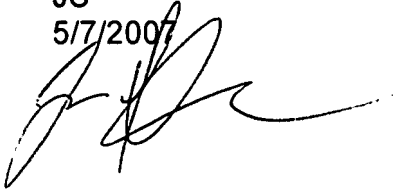
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Art Unit: 3762

Joseph Stoklosa
Examiner
Art Unit 3762

JS

5/7/2007




GEORGE R. EVANISKO
PRIMARY EXAMINER

5/10/17